

Michael J. McCue (Nevada Bar #6055)
Jonathan W. Fountain (Nevada Bar #10351)
Meng Zhong (Nevada Bar # 12145)
LEWIS ROCA ROTHGERBER LLP
3993 Howard Hughes Parkway, Suite 600
Las Vegas, NV 89169-5996
(702) 949-8200 (phone)
(702) 949-8398 (facsimile)
mmccue@lrrlaw.com
jfountain@lrrlaw.com
mzhong@lrrlaw.com

Mark H. Izraelewicz (*pro hac vice*)
Thomas I. Ross (*pro hac vice*)
Kevin M. Flowers (*pro hac vice*)
John R. Labbe (*pro hac vice*)
Amanda K. Antons (*pro hac vice*)
MARSHALL, GERSTEIN & BORUN LLP
233 South Wacker Drive
6300 Willis Tower
Chicago, IL 60606-6357
(312) 474-6300 (phone)
(312) 474-0448 (facsimile)
mizraelewicz@marshallip.com
tross@marshallip.com
kflowers@marshallip.com
jlabbe@marshallip.com
aantons@marshallip.com

Attorneys for Plaintiffs
SPECTRUM PHARMACEUTICALS, INC.
and UNIVERSITY OF STRATHCLYDE

UNITED STATES DISTRICT COURT

DISTRICT OF NEVADA

SPECTRUM PHARMACEUTICALS, INC.)
and UNIVERSITY OF STRATHCLYDE,)
Plaintiffs,)
v.)
BEN VENUE LABORATORIES, INC. d/b/a)
BEDFORD LABORATORIES,)
Defendant.)

Case No: 2:14-cv-00980-GMN-PAL

**JOINT MOTION FOR
SUBSTITUTION OF PARTIES AND
PLAINTIFFS' MOTION FOR LEAVE
TO FILE FIRST AMENDED
COMPLAINT AND [PROPOSED]
ORDER**

1 Plaintiffs Spectrum Pharmaceuticals, Inc. (“Spectrum”) and University of Strathclyde
2 (“Strathclyde”) (collectively “Plaintiffs”), Defendant Ben Venue Laboratories, Inc. d/b/a Bedford
3 Laboratories (“Ben Venue”), and West-Ward Pharmaceutical Corp. (“West-Ward”) and
4 Eurohealth International Sarl (“Eurohealth”) jointly move the court under Fed. R. Civ. P. 25(c)
5 for a substitution of parties. Additionally, Plaintiffs move the court under Fed. R. Civ. P.
6 15(a)(2) for leave to file a First Amended Complaint (attached hereto as Exhibit B), which Ben
7 Venue, West-Ward, and Eurohealth do not oppose.

8 Plaintiffs, Ben Venue, West-Ward, and Eurohealth have agreed to the stipulation attached
9 as Exhibit A and respectfully request that the Court enter the following Proposed Order:

Dated: November 20, 2014

/s/ Mark H. Izraelewicz

/s/ William G. James

Michael J. McCue (Nevada Bar #6055)
Jonathan W. Fountain (Nevada Bar #10351)
Meng Zhong (Nevada Bar # 12145)
LEWIS ROCA ROTHGERBER LLP
3993 Howard Hughes Parkway, Suite 600
Las Vegas, NV 89169-5996
(702) 949-8200 (phone)
(702) 949-8398 (facsimile)
mmccue@lrrlaw.com
jfountain@lrrlaw.com
mzhong@lrrlaw.com

Jacob A. Reynolds (Bar No. 10199)
HUTCHINSON & STEFFEN, LLC
10080 W. Alta Drive, Suite 200
Las Vegas, NV 89145
(702) 385-2500
jreynolds@hutchlegal.com

Philip A. Kantor (Bar No. 6701)
LAW OFFICES OF PHILIP A. KANTOR, P.C.
1781 Village Center Circle, Suite 120
Las Vegas, Nevada 89134-0120
(702) 255-1300
prsak@aya.yale.edu

Mark H. Izraelewicz (*pro hac vice*)
Thomas I. Ross (*pro hac vice*)
Kevin M. Flowers (*pro hac vice*)
John R. Labbe (*pro hac vice*)
Amanda Antons (*pro hac vice*)
MARSHALL, GERSTEIN & BORUN LLP
233 South Wacker Drive
6300 Willis Tower
Chicago, IL 60606-6357
(312) 474-6300 (phone)
(312) 474-0448 (facsimile)
mizraelewicz@marshallip.com
tross@marshallip.com
kflowers@marshallip.com
jlabbe@marshallip.com
aantons@marshallip.com

William G. James (*pro hac vice*)
J. Coy Stull (*pro hac vice*)
GOODWIN PROCTER LLP
901 New York Avenue, NW
Washington, DC 20001
(202) 346-4046
wjames@goodwinprocter.com

Attorneys for BEN VENUE
LABORATORIES, INC. d/b/a BEDFORD
LABORATORIES, WEST-WARD
PHARMACEUTICAL CORP., and
EUROHEALTH INTERNATIONAL SARL

Attorneys for Plaintiffs
SPECTRUM PHARMACEUTICALS, INC.
and UNIVERSITY OF STRATHCLYDE

[PROPOSED] ORDER

WHEREAS Plaintiffs Spectrum Pharmaceuticals, Inc. (“Spectrum”) and University of Strathclyde (“Strathclyde”) (collectively “Plaintiffs”), Defendant Ben Venue Laboratories, Inc. d/b/a Bedford Laboratories (“Ben Venue”), West-Ward Pharmaceutical Corp. (“West-Ward”), and Eurohealth International Sarl (“Eurohealth”) have entered into a Stipulation Regarding Substitution of Parties and Amended Complaint dated November 20, 2014 (“Stipulation”);

WHEREAS the Court takes notice of the facts to which the Plaintiffs, Ben Venue, West-Ward, and Eurohealth have stipulated and enters the following Order in reliance thereon; and

THE COURT HEREBY ORDERS AS FOLLOWS:

1. Pursuant to Federal Rule of Civil Procedure 25(c), West-Ward and Eurohealth are substituted as defendants in this case in place of Ben Venue;

2. Pursuant to Federal Rule of Civil Procedure 15(a)(2), Plaintiffs are granted leave to file their First Amended Complaint in the form of Exhibit B attached to the accompanying stipulation; and

3. The case caption shall hereafter be styled as follows:

SPECTRUM PHARMACEUTICALS, INC.)
AND UNIVERSITY OF STRATHCLYDE,)

Plaintiffs,)

v.)

EUROHEALTH INTERNATIONAL SARL)
AND WEST-WARD PHARMACEUTICAL)
CORP.)

Defendants.)

Case No:14-cv-00980-GMN-PAL

EUROHEALTH INTERNATIONAL SARL,)
AND WEST-WARD PHARMACEUTICAL)
CORP.)

Counterclaimants,)

v.)

SPECTRUM PHARMACEUTICALS, INC.)
AND UNIVERSITY OF STRATHCLYDE,)

Counterdefendants.)

IT IS SO ORDERED


UNITED STATES MAGISTRATE JUDGE

DATED: November 24, 2014

CERTIFICATE OF SERVICE

I hereby certify that on November 20, 2014, I filed the foregoing document entitled, JOINT MOTION FOR SUBSTITUTION OF PARTIES AND PLAINTIFFS' MOTION FOR LEAVE TO FILE FIRST AMENDED COMPLAINT AND [PROPOSED] ORDER, with the Clerk of the Court via the Court's CM/ECF system, which will send electronic notice of the same to the following counsel of record:

- William G. James Esq. (wjames@goodwinprocter.com);
- Phillip A. Kantor, Esq. (prsak@aya.yale.edu);
- Jacob A. Reynolds, Esq. (jreynolds@hutchlegal.com); and
- John Coy Stull, Esq. (jstull@goodwinprocter.com).

Dated: this 20th day of November, 2014

/s/ John R. Labbé
Attorney for Plaintiffs

EXHIBIT A

Michael J. McCue (Nevada Bar #6055)
Jonathan W. Fountain (Nevada Bar #10351)
Meng Zhong (Nevada Bar # 12145)
LEWIS ROCA ROTHGERBER LLP
3993 Howard Hughes Parkway, Suite 600
Las Vegas, NV 89169-5996
(702) 949-8200 (phone)
(702) 949-8398 (facsimile)
mmccue@lrrlaw.com
jfountain@lrrlaw.com
mzhong@lrrlaw.com

Mark H. Izraelewicz (*pro hac vice*)
Thomas I. Ross (*pro hac vice*)
Kevin M. Flowers (*pro hac vice*)
John R. Labbe (*pro hac vice*)
Amanda K. Antons (*pro hac vice*)
MARSHALL, GERSTEIN & BORUN LLP
233 South Wacker Drive
6300 Willis Tower
Chicago, IL 60606-6357
(312) 474-6300 (phone)
(312) 474-0448 (facsimile)
mizraelewicz@marshallip.com
tross@marshallip.com
kflowers@marshallip.com
jlabbe@marshallip.com
aantons@marshallip.com

Attorneys for Plaintiffs
SPECTRUM PHARMACEUTICALS, INC.
and UNIVERSITY OF STRATHCLYDE

UNITED STATES DISTRICT COURT

DISTRICT OF NEVADA

SPECTRUM PHARMACEUTICALS, INC.)
and UNIVERSITY OF STRATHCLYDE,)
)
Plaintiffs,)
)
v.)
)
BEN VENUE LABORATORIES, INC. d/b/a)
BEDFORD LABORATORIES,)
)
Defendant.)

Case No: 2:14-cv-00980-GMN-PAL

**STIPULATION REGARDING
SUBSTITUTION OF PARTIES AND
AMENDED COMPLAINT**

1 Plaintiffs Spectrum Pharmaceuticals, Inc. (“Spectrum”) and University of Strathclyde
2 (“Strathclyde”) (collectively “Plaintiffs”), Defendant Ben Venue Laboratories, Inc. d/b/a Bedford
3 Laboratories (“Ben Venue”), and West-Ward Pharmaceutical Corp. (“West-Ward”) and
4 Eurohealth International Sarl (“Eurohealth”) hereby STIPULATE to the following facts:

5 1. On or about July 15, 2014, Hikma Pharmaceuticals PLC (“Hikma”) acquired all
6 the assets of the Bedford Laboratories division of Ben Venue either directly or through one or
7 more of its wholly-owned subsidiaries.

8 2. On or about July 15, 2014, Ben Venue divested itself of all right, title, and interest
9 in ANDA No. 260263. Eurohealth is now the sole owner of ANDA No. 260263. Eurohealth has
10 informed the Food and Drug Administration of its commitment to all agreements, promises, and
11 conditions made by the former owner and contained in the ANDA, and that it has appointed
12 West-Ward Pharmaceutical Corp. as its U.S. Agent for the ANDA.

13 3. In view of the above, under 35 U.S.C. § 271(e)(2), Plaintiffs’ Complaint in this
14 case is properly filed against Eurohealth, the new owner of ANDA No. 260263, and West-Ward,
15 its U.S. Agent for the ANDA.

16 4. West-Ward and Eurohealth seek to market, manufacture, and sell in the United
17 States a generic form of Spectrum’s pharmaceutical product Fusilev[®], prior to the expiration of
18 United States Patent No. 6,500,829 (“the ‘829 patent”). Plaintiffs contend that West-Ward and
19 Eurohealth’s marketing, manufacturing, and sale of a generic form of Fusilev[®] would infringe
20 the ‘829 patent and Plaintiffs contend that the ‘829 patent is valid and enforceable. Therefore,
21 under 28 U.S.C. §§ 2201-2201, an actual and justiciable controversy exists between Plaintiffs
22 and West-Ward and Eurohealth regarding the infringement and validity of the ‘829 patent.

23 5. Hikma is a company incorporated in the United Kingdom with a place of business
24 at 13 Hanover Square, London, W1S 1HW, United Kingdom. Hikma is a worldwide
25 pharmaceutical company in the business of developing and manufacturing branded and generic
26 drugs.

27 6. Eurohealth is a wholly-owned subsidiary of Hikma organized under the laws of
28 Switzerland. Eurohealth is the owner of ANDA No. 206263 at issue in this case.

1 7. West-Ward is a corporation organized and existing under the laws of the State of
2 Delaware with a principal place of business at 401 Industrial Way West, Eatontown, New Jersey
3 07724. West-Ward acts as a marketer, manufacturer, and distributor of drug products for sale and
4 use throughout the United States for Hikma and its affiliated entities including Eurohealth. West-
5 Ward is an indirect wholly-owned subsidiary of Hikma.

6 8. West-Ward and Eurohealth each consent to this Court's personal jurisdiction over
7 each of them for purposes of this action only. West-Ward and Eurohealth further consent that
8 venue is proper in this judicial district for purposes of this action only.

9 9. Eurohealth agrees not to challenge or otherwise assert that the FDA's statutory
10 30-month stay of approval with respect to ANDA No. 206263 is terminated, waived, or lifted,
11 based upon the transfer of ANDA No. 206263 to Eurohealth. Further, Eurohealth agrees that it
12 remains subject to all applicable FDA rules, regulations, orders, and stays as if it were the
13 original filer of ANDA No. 206263.

14 10. Ben Venue stipulates that it has used its best efforts to transfer documents and
15 information in its custody or control and relating to the subject matter of this action to
16 Eurohealth's and/or West-Ward's custody or control. Eurohealth and/or West-Ward agree to
17 produce such documents and information in response to Plaintiffs' discovery requests, to the
18 extent they are relevant, responsive to Plaintiffs' discovery requests, and non-privileged.

19 11. The below-signed counsel for defendant Ben Venue is also counsel for each of
20 West-Ward and Eurohealth, and is authorized to enter this stipulation on behalf of each of Ben
21 Venue, West-Ward, and Eurohealth.

22 12. Ben Venue, West-Ward, and Eurohealth consent to Plaintiffs' motion for leave to
23 file their First Amended Complaint. The First Amended Complaint is attached hereto as Exhibit
24 B.

25 13. Plaintiffs, Ben Venue, West-Ward, and Eurohealth agree that under Federal Rule
26 of Civil Procedure 25(c), West-Ward and Eurohealth should be substituted as defendants in this
27 case in place of Ben Venue.

28 14. Plaintiffs, Ben Venue, West-Ward, and Eurohealth agree that the case caption

1 should hereafter be styled as follows:

2
3 SPECTRUM PHARMACEUTICALS, INC.
4 AND UNIVERSITY OF STRATHCLYDE,

5 Plaintiffs,

6 v.

7 EUROHEALTH INTERNATIONAL SARL
8 AND WEST-WARD PHARMACEUTICAL
9 CORP.,

10 Defendants.

11 EUROHEALTH INTERNATIONAL SARL
12 AND WEST-WARD PHARMACEUTICAL
13 CORP.,

14 Counterclaimants,

15 v.

16 SPECTRUM PHARMACEUTICALS, INC.
17 AND UNIVERSITY OF STRATHCLYDE,

18 Counterdefendants.

Case No: 2:14-cv-00980-GMN-PAL

STIPULATED AND AGREED

Dated: November 20, 2014

/s/ Mark H. Izraelewicz

/s/ William G. James

Michael J. McCue (Nevada Bar #6055)
Jonathan W. Fountain (Nevada Bar #10351)
Meng Zhong (Nevada Bar # 12145)
LEWIS ROCA ROTHGERBER LLP
3993 Howard Hughes Parkway, Suite 600
Las Vegas, NV 89169-5996
(702) 949-8200 (phone)
(702) 949-8398 (facsimile)
mmccue@lrrlaw.com
jfountain@lrrlaw.com
mzhong@lrrlaw.com

Jacob A. Reynolds (Bar No. 10199)
HUTCHINSON & STEFFEN, LLC
10080 W. Alta Drive, Suite 200
Las Vegas, NV 89145
(702) 385-2500
jreynolds@hutchlegal.com

Philip A. Kantor (Bar No. 6701)
LAW OFFICES OF PHILIP A. KANTOR, P.C.
1781 Village Center Circle, Suite 120
Las Vegas, Nevada 89134-0120
(702) 255-1300
prsak@aya.yale.edu

Mark H. Izraelewicz (*pro hac vice*)
Thomas I. Ross (*pro hac vice*)
Kevin M. Flowers (*pro hac vice*)
John R. Labbe (*pro hac vice*)
Amanda Antons (*pro hac vice*)
MARSHALL, GERSTEIN & BORUN LLP
233 South Wacker Drive
6300 Willis Tower
Chicago, IL 60606-6357
(312) 474-6300 (phone)
(312) 474-0448 (facsimile)
mizraelewicz@marshallip.com
tross@marshallip.com
kflowers@marshallip.com
jlabbe@marshallip.com
aantons@marshallip.com

William G. James (*pro hac vice*)
J. Coy Stull (*pro hac vice*)
GOODWIN PROCTER LLP
901 New York Avenue, NW
Washington, DC 20001
(202) 346-4046
wjames@goodwinprocter.com

Attorneys for BEN VENUE
LABORATORIES, INC. d/b/a BEDFORD
LABORATORIES, WEST-WARD
PHARMACEUTICAL CORP., and
EUROHEALTH INTERNATIONAL SARL

Attorneys for Plaintiffs
SPECTRUM PHARMACEUTICALS, INC.
and UNIVERSITY OF STRATHCLYDE

EXHIBIT B

Michael J. McCue (Nevada Bar #6055)
Jonathan W. Fountain (Nevada Bar #10351)
Meng Zhong (Nevada Bar # 12145)
LEWIS ROCA ROTHGERBER LLP
3993 Howard Hughes Parkway, Suite 600
Las Vegas, NV 89169-5996
(702) 949-8200 (phone)
(702) 949-8398 (facsimile)
mmccue@lrrlaw.com
jfountain@lrrlaw.com
mzhong@lrrlaw.com

Mark H. Izraelewicz (*pro hac vice*)
Thomas I. Ross (*pro hac vice*)
Kevin M. Flowers (*pro hac vice*)
John R. Labbe (*pro hac vice*)
Amanda K. Antons (*pro hac vice*)
MARSHALL, GERSTEIN & BORUN LLP
233 South Wacker Drive
6300 Willis Tower
Chicago, IL 60606-6357
(312) 474-6300 (phone)
(312) 474-0448 (facsimile)
mizraelewicz@marshallip.com
tross@marshallip.com
kflowers@marshallip.com
jlabbe@marshallip.com
aantons@marshallip.com

Attorneys for Plaintiffs
SPECTRUM PHARMACEUTICALS, INC.
and UNIVERSITY OF STRATHCLYDE

UNITED STATES DISTRICT COURT

DISTRICT OF NEVADA

SPECTRUM PHARMACEUTICALS, INC.)
and UNIVERSITY OF STRATHCLYDE,)

Plaintiffs,)

v.)

WEST-WARD PHARMACEUTICAL CORP.)
and EUROHEALTH INTERNATIONAL SARL)

Defendants.)

**FIRST AMENDED COMPLAINT
FOR PATENT INFRINGEMENT**

1 Plaintiffs Spectrum Pharmaceuticals, Inc. (“Spectrum”) and University of Strathclyde
2 (“Strathclyde”) (collectively “Plaintiffs”) for their Complaint against Defendants West-Ward
3 Pharmaceutical Corp. (“West-Ward”) and Eurohealth International Sarl (“Eurohealth”)
4 (collectively “Defendants”), allege:

5 **NATURE OF THE ACTION**

6 1. This is an action for patent infringement under the patent laws of the United
7 States, 35 U.S.C. § 100 et seq., including 35 U.S.C. § 271(e)(2), and the Declaratory Judgment
8 Act, 28 U.S.C. §§ 2201 and 2202, arising from Ben Venue Laboratories, Inc.’s (“Ben Venue”)
9 filing of an Abbreviated New Drug Application (“ANDA”) under Section 505(j) of the Federal
10 Food, Drug and Cosmetic Act, 21 U.S.C. § 355(j), seeking U.S. Food and Drug Administration
11 (“FDA”) approval to market a levoleucovorin product, which is a generic form of Spectrum’s
12 pharmaceutical product Fusilev[®], prior to the expiration of United States Patent No. 6,500,829
13 (“the ‘829 patent”), which covers Fusilev[®].

14 **THE PARTIES**

15 2. Spectrum is a Delaware corporation having its principal place of business at
16 11500 South Eastern Avenue, Suite 240, Henderson, Nevada 89052. Spectrum is engaged in the
17 business of research, development, manufacture, and sale of pharmaceutical products.

18 3. Strathclyde, incorporated by Royal Charter of Queen Elisabeth II, is a charitable
19 body registered in Scotland with registration number SC015263, having its principal place of
20 business at 16 Richmond Street, Glasgow G1 1XQ, Scotland, United Kingdom.

21 4. On information and belief, Defendant West-Ward is a corporation organized and
22 existing under the laws of the State of Delaware with a principal place of business at 401
23 Industrial Way West, Eatontown, New Jersey 07724. Upon information and belief, West-Ward
24 acts as a marketer, manufacturer, and distributor of drug products for sale and use throughout the
25 United States for Hikma Pharmaceuticals PLC (“Hikma”), West-Ward’s parent company, and its
26 affiliated entities including Eurohealth. According to West-Ward’s website, West-Ward is “the
27 US agent and subsidiary of Hikma PLC.”

28 5. Upon information and belief, Eurohealth is a wholly-owned subsidiary of Hikma

1 organized under the laws of Switzerland. Eurohealth is the owner of ANDA No. 206263 at issue
2 in this case.

3 **JURISDICTION AND VENUE**

4 6. This Court has subject-matter jurisdiction over this action pursuant to 28 U.S.C.
5 §§ 1331, 1338(a), 2201 and 2202.

6 7. This Court has personal jurisdiction over each of the Defendants because by a
7 stipulation entered on November 20, 2014 as Docket Entry No. 45 each of the Defendants
8 consented to personal jurisdiction for purposes of this action only.

9 8. On information and belief, West-Ward applied for, and received, a license from
10 the Nevada Board of Pharmacy to act as a pharmaceutical wholesaler in Nevada. On information
11 and belief, West-Ward is currently a registered “Wholesaler” of drug products with the Nevada
12 Board of Pharmacy, and distributes drug products throughout the State of Nevada. West-Ward
13 directly and/or through its affiliated companies in the Hikma group of companies has systematic
14 and continuous contacts with the State of Nevada, by including, among other things, selling
15 pharmaceutical products to residents of Nevada and to others with the intent that those products
16 are marketed and distributed in Nevada, and receiving significant revenue for the sale of those
17 products in Nevada.

18 9. Venue is proper in this District because by a stipulation entered on November 20,
19 2014 as Docket Entry No. 45 each of the Defendants admitted that venue is proper for purposes of
20 this action only.

21 10. Venue is proper in this District pursuant to 28 U.S.C. §§ 1391(c) and 1400(b).

22 **THE PATENT-IN-SUIT**

23 11. On December 31, 2002, the United States Patent and Trademark Office issued
24 U.S. Patent No. 6,500,829, entitled “Substantially Pure Diastereoisomers of Tetrahydrofolate
25 Derivatives.” At the time of its issue, the ‘829 patent was assigned to Strathclyde. Strathclyde
26 currently holds title to the ‘829 patent. Strathclyde has exclusively licensed the ‘829 patent to
27 Spectrum. A copy of the ‘829 patent is attached hereto as Exhibit A.

28 12. The claims of the ‘829 patent are valid and enforceable.

FUSILEV[®]

13. Spectrum holds New Drug Application No. 20-140 (initially approved on March 7, 2008) (“the Fusilev[®] NDA”) approving Spectrum to market a levoleucovorin product as a lyophilized powder in a 50 mg dosage strength, which is marketed by Spectrum under the trade name Fusilev[®].

14. On November 7, 2011, the FDA granted Fusilev[®] seven years of orphan-drug exclusive approval pursuant to Section 527 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 360cc) for use in combination chemotherapy with 5-fluorouracil in the palliative treatment of advanced metastatic adenocarcinoma of the colon and rectum.

15. Pursuant to 21 U.S.C. § 355(b)(1) and attendant FDA regulations, the ‘829 patent is listed in the FDA publication “Approved Drug Products with Therapeutic Equivalence Evaluations” (“the Orange Book”) with respect to Fusilev[®].

DEFENDANTS’ ANDA

16. On information and belief, Ben Venue submitted an Abbreviated New Drug Application, ANDA No. 206263, to the FDA, pursuant to 21 U.S.C. §§ 355(j), seeking approval to market levoleucovorin calcium for injection, 50 mg/vial.

17. Upon information and belief, on or about July 15, 2014, Hikma acquired all the assets of Bedford either directly or through one or more of its wholly-owned subsidiaries.

18. Upon information and belief, on or about July 15, 2014, Ben Venue transferred all right, title, and interest in ANDA No. 260263 to Eurohealth. Accordingly, Eurohealth is now the sole owner of ANDA No. 260263. Eurohealth has assumed all liability of Ben Venue incurred as a result of Ben Venue’s submission of ANDA No. 260263 to the FDA.

19. Upon information and belief, Ben Venue and Eurohealth informed the FDA of the transfer of ownership of ANDA No. 260263, and identified West-Ward as Eurohealth’s authorized agent in the United States.

20. ANDA No. 260263 is hereinafter referred to as “Defendants’ ANDA.” The levoleucovorin vial described in Defendants’ ANDA is herein referred to as “Defendants’ Product.”

21. On information and belief, Defendants' ANDA refers to and relies upon the Fusilev[®] NDA and/or the Fusilev[®] sNDA and contains data that, according to Defendants, demonstrates the bioequivalence of Defendants' Product and Fusilev[®].

22. By filing Defendants' ANDA, Defendants have necessarily represented to the FDA that Defendants' Product has the same active ingredient as Fusilev[®], has the same route of administration, dosage form, and strength as Fusilev[®], is bioequivalent to Fusilev[®], and has the same or substantially the same proposed labeling as Fusilev[®].

23. Spectrum received a letter from Ben Venue on or around June 11, 2014 ("Defendants' Notification"), stating that Ben Venue had included a certification in Defendants' ANDA, pursuant to 21 U.S.C. §355(j)(2)(A)(vii)(IV), that the '829 patent is invalid, unenforceable, or will not be infringed by the commercial manufacture, use, or sale of Defendants' Product.

24. Plaintiffs filed this action within forty-five days from the date that Spectrum received Defendants' Notification.

COUNT FOR INFRINGEMENT OF U.S. PATENT NO. 6,500,829

25. Plaintiffs reallege and incorporate by reference the allegations of paragraphs 1-24 of this Complaint.

26. The '829 patent contains claims directed to, for example (claim 1), "A pharmaceutical composition for therapeutic use which consists essentially of a therapeutically effective amount sufficient for the treatment of human beings for methotrexate rescue or folate deficiency, of a pharmaceutically acceptable compound which is a (6S) diastereoisomer selected from the group consisting of (6S) leucovorin (5-formyl-(6S)-tetrahydrofolic acid) and pharmaceutically acceptable salts and esters of (6S) leucovorin; wherein the compound consists of a mixture of (6S) and (6R) diastereoisomers and consists of at least 92% by weight of the (6S) diastereoisomer, the balance of said compound consisting of the (6R) diastereoisomer; in combination with a pharmaceutically acceptable carrier."

27. Defendants infringe claims 1 and 2 of the '829 patent, and do not deny such infringement in Defendants' Notification.

28. Eurohealth, as successor in interest to Ben Venue with regard ANDA No. 260263, has committed an act of infringement under 35 U.S.C. § 271(e)(2)(A) by submitting ANDA No. 260263, seeking approval from the FDA to engage in the commercial manufacture, use, offer to sell, sale, or importation of Defendants' Product prior to the expiration of the '829 patent.

29. Defendants' commercial manufacture, use, offer to sell, or sale of Defendants' Product within the United States, or importation of Defendants' Product into the United States, during the term of the '829 patent would further infringe one or more claims of the '829 patent under 35 U.S.C. §§ 271(a), (b), and/or (c).

30. Defendants' filing of Defendants' ANDA and its intention to engage in the commercial manufacture, use, offer to sell, sale, or importation of Defendants' Product upon receiving FDA approval creates an actual case or controversy with respect to infringement of the '829 patent.

31. Plaintiffs are entitled to the relief provided by 35 U.S.C. § 271(e)(4), including an order of this Court that the effective date of any approval relating to Defendants' ANDA shall not be earlier than March 7, 2022, the current expiration date of the '829 patent, or any later expiration date to which Plaintiffs become entitled.

32. This is an exceptional case, and Plaintiffs are entitled to an award of attorneys' fees, under 35 U.S.C. § 285.

REQUEST FOR RELIEF

WHEREFORE, Plaintiffs request that this Court grant the following relief:

- A. A declaration that the '829 patent is valid and enforceable;
- B. A declaration that by filing Defendants' ANDA, Eurohealth has infringed one or more claims of the '829 patent under 35 U.S.C. § 271(e)(2)(A);
- C. A declaration that one or more claims of the '829 patent would be infringed by the manufacture, use, offer for sale, or sale of Defendants' Product within the United States, or by importation of Defendants' Product into the United States;
- D. An Order preliminarily and permanently enjoining Defendants, their officers, agents, servants, and employees, and those persons in active concert or participation with any of

1 them, from manufacturing, using, offering to sell, or selling Defendants' Product within the
2 United States, or importing Defendants' Product into the United States, prior to the expiration of
3 the '829 patent (including any extensions thereof);

4 E. An Order prohibiting Defendants, their officers, agents, servants, and employees,
5 and those persons in active concert or participation with any of them, from seeking, obtaining, or
6 maintaining approval of Defendants' ANDA, prior to the expiration of the '829 patent (including
7 any extensions thereof);

8 F. A declaration that the effective date of any approval of Defendants' ANDA under
9 § 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)) shall not be earlier
10 than the expiration date of the '829 patent (including any extensions thereof);

11 G. A judgment awarding Plaintiffs damages or other monetary relief if any of the
12 Defendants commercially manufactures, uses, offers to sell, or sells Defendants' Product within
13 the United States, or imports Defendants' Product into the United States, prior to the expiration
14 of the '829 patent (including any extensions thereof), and that any such damages or monetary
15 relief be trebled and awarded to Plaintiffs with prejudgment interest;

16 H. A declaration that this is an exceptional case and a judgment awarding Plaintiffs
17 their reasonable attorneys' fees incurred in this action pursuant to 35 U.S.C. § 285 and 271(e)(4);

18 I. Reasonable filing fees, costs and expenses incurred by Plaintiffs in this action;
19 and

20 J. Such further and other relief as this Court deems just and proper.

21
22 Dated: November ___, 2014

23 Respectfully submitted,

24 LEWIS ROCA ROTHGERBER LLP

25
26

Michael J. McCue (Bar No. 6055)
27 Jonathan W. Fountain (Bar No. 10351)
28 LEWIS AND ROCA LLP
3993 Howard Hughes Parkway, Suite 600
Las Vegas, NV 89169-5996
(702) 949-8200 (phone)

(702) 949-8398 (facsimile)
mmccue@lrlaw.com
jfountain@lrlaw.com

Mark H. Izraelewicz (*pro hac vice*)
Thomas I. Ross (*pro hac vice*)
Kevin M. Flowers (*pro hac vice*)
John R. Labbe (*pro hac vice*)
Amanda K. Antons (*pro hac vice*)
MARSHALL, GERSTEIN & BORUN LLP
233 South Wacker Drive
6300 Willis Tower
Chicago, IL 60606-6357
(312) 474-6300 (phone)
(312) 474-0448 (facsimile)
mizraelewicz@marshallip.com
tross@marshallip.com
kflowers@marshallip.com
jlabbe@marshallip.com
aantons@marshallip.com

Attorneys for Plaintiffs
SPECTRUM PHARMACEUTICALS, INC.
and UNIVERSITY OF STRATHCLYDE